

POLY-VI-FLOR WITH IRON- multivitamin and fluoride supplement suspension/ drops
Aytu Therapeutics, LLC

Poly-Vi-Flor with Iron

Multivitamin and Fluoride Supplement

Supplement Facts		
Serving Size 1 mL Dropperful		
Daily		
Servings Per Container - 50		
	% Daily Value	
	Children	
	Under Age 4	
Amount Per 1 mL	Infants	Years
Vitamin D ₃ (as Cholecalciferol) 400 IU	100%	100%
Vitamin E (as Alpha Tocopheryl Acetate) 5 IU	100%	50%
Vitamin B ₁ (as Thiamine HCl) 0.5 mg	100%	71%
Vitamin B ₂ (as Riboflavin) 0.6 mg	100%	75%
Niacin (Vitamin B3) (as Niacinamide) 8 mg	100%	89%
Vitamin B ₆ (as Pyridoxine HCl) 0.4 mg	100%	57%
Folate (as Calcium L-methylfolate (Metafolin [®])) 200 mcg	162%	81%
Iron (as Ferric Saccharate, with Alginates) 7 mg	47%	70%
Fluoride (as sodium fluoride) 0.25 mg	*	*

*U.S. Recommended Daily Allowance has not been established

OTHER INGREDIENTS: Glycerin, Water, Fructose, Xylitol, Polysorbate 80, Natural Flavoring, Citric Acid, Soy Lecithin, Potassium Sorbate, Sodium Benzoate

Distributed by: Zylera Pharmaceuticals
Research Triangle Park, NC 27713

U.S. Patent No. 5,997,915 • U.S. Patent No. 6,254,904
U.S. Patent No. 6,011,040 • U.S. Patent No. 6,441,168

Metafolin[®] is a registered trademark of Merck KGaA, Darmstadt, Germany *CAS# 151533-22-1

QUESTIONS OR COMMENTS? Please call Zylera Medical Affairs at 1-866-416-9637

WARNING

Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. In case of accidental overdose, call a poison control center immediately.

How to Use the Enclosed Dropper

Fill the dropper to the **1 mL** line to provide the full daily dosage. Use full dosage, regardless of age or weight, unless your child's doctor recommends a different dosage. Dispense with a single squeeze.

Dosing Tips

Drops may be given by dispensing directly into the mouth. Drops may also be mixed with formula, fruit juice, cereal or other foods to increase your child's acceptance.

Shake well before use.

This product comes with a child-resistant cap. Refrigeration not required. After opening, store away from direct sunlight.

WARNING

As with medicines, keep out of the reach of children.

PRINCIPAL DISPLAY PANEL - Poly-Vi-Flor with Iron and 0.25 mg of Fluoride

23594-600-50

Poly-Vi-Flor with Iron

Essential Vitamins for Infants & Toddlers

FRUITY FLAVOR

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

0.25 mg with iron

NEW FORMULATION

NOT SUBSTITUTABLE

CONTAINS: METAFOLIN

1 2/3 FL OZ (50 mL)

Zylera Pharmaceuticals

23594-600-50

Poly-Vi-Flor
with iron

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Zylera
PHARMACEUTICALS

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Servings Per Container - 50

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Vitamin B ₂ (as Riboflavin) 0.6 mg	100%
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Vitamin B ₆ (as Pyridoxine HCl) 0.4 mg	100%
Folate (as Calcium - Methylfolate (Methfolin)) 200 mcg	57%
Iron (as Ferrous Succinate, with Myristes) 7 mg	81%
Fluoride (as Sodium Fluoride) 0.25 mg	47%

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OTHER INGREDIENTS: Glycerin, Water, Fructose, Xylitol, Polysorbate 80, Natural Flavoring, Citric Acid, Soy Lecithin, Potassium Sorbate, Sodium Benzoate.

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POLY-VI-FLOR WITH IRON

multivitamin and fluoride supplement suspension/ drops

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:23594-600
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU] in 50 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE	5 [iU] in 50 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	0.5 mg in 50 mL
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	0.6 mg in 50 mL
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	8 mg in 50 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	0.4 mg in 50 mL
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	200 ug in 50 mL
IRON SUCROSE (UNII: FZ7NYF5N8L) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	7 mg in 50 mL
FLUORIDE ION (UNII: Q80VPU408O) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 50 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FRUCTOSE (UNII: 6YSS42VSEV)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:23594-600-50	1 in 1 PACKAGE		
1		50 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

dietary supplement		09/01/2016	
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Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
flavor	

Labeler - Aytu Therapeutics, LLC (117244733)

Revised: 4/2019

Aytu Therapeutics, LLC